

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
9 June 2005 (09.06.2005)

PCT

(10) International Publication Number
WO 2005/051344 A3

- (51) International Patent Classification⁷: A61K 31/58,
9/28, 9/20, 9/48
- (21) International Application Number:
PCT/CZ2004/000078
- (22) International Filing Date:
23 November 2004 (23.11.2004)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:
PV 2003-3216 25 November 2003 (25.11.2003) CZ
- (71) Applicant (for all designated States except US): PLIVA-LACHEMA A.S. [CZJCL]; Karasek 1, 621 33 Brno (CZ).
- (72) Inventors; and
- (75) Inventors/Applicants (for US only): FRANC, Ales [CZJCL]; Purkynova 19, 612 00 Brno (CZ). ZALUDEK, Borek [CZJCL]; Novomestska 19, 621 00 Brno (CZ). GONEC, Roman [CZJCL]; Gruzinska 11, 625 00 Brno (CZ). MATEJKOVA, Bozena [CZJCL]; Stouracova 12, 635 00 Brno (CZ). PETROVICOVA, Anna [CZJCL]; Moravske namesti 12, 602 00 Brno (CZ).
- (74) Agent: KUBAT, Jan; Traplova Hakr Kubat, Law and Patent Offices, P.O. Box 38, Pristavni 24, 170 00 Praha 7 (CZ).
- (81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW
- (84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).
- Declarations under Rule 4.17:**
- as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(U))
 - of inventorship (Rule 4.17(iv))
- Published:**
- with international search report
 - with amended claims
- (88) Date of publication of the international search report: 9 September 2005

Date of publication of the amended claims: 20 April 2006

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: ORAL SOLID INSTANT-RELEASE DOSAGE FORMS COMPRISING FINASTERIDE AND AN ANIONIC SURFACTANT-METHODS OF MANUFACTURING THEREOF

(57) **Abstract:** A method of preparation of an oral solid dosage form with instant release of an active agent containing as the active agent finasteride characterized in that an aqueous suspension containing 5 % to 50 % by weight of finasteride, based on the total weight of the suspension, and 0.1% to 50 % by weight of at least one anion surfactant, based on the weight of finasteride is milled in order to reach such distribution of particle size of finasteride that the size of 10 % of particles does not exceed 2 µm, the size of 50 % of particles does not exceed 7 µm, and the size of 90 % of particles does not exceed 17 µm, then the obtained aqueous suspension is sprayed to a fluid bed onto a solid particle hydrophilic carrier having such distribution of particle size that the size of 90 % of particles exceeds 40 µm and the size of 10 of particles exceeds 200 µm, and the size of 99 % of particles does not exceed 300 µm.

WO 2005/051344 A3